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I. BACKGROUND

Vital Pharm manufactures and sells a variety of energy drinks and related products under the brand name of Redline ®. Redline's active ingredients include beta-alanine, caffeine, vitamin C, N-Acetyl-LTyrosine, potassium citrate, yohimbine HCI, B-Phenylethylamine HCI, N-methyl Tyramine, Evodiamine, Sulbutiamine, 5-Hydroxy-L-Tryptophan, yerba mate, green tea, vinpocetine, and hypericin. (*Req. for Jud. Not.*, Ex. A.) Aaronson purchased and used Redline several times in 2008. Aaronson claims later to have learned that Redline was not safe.

On June 16, 2009, Aaronson filed the present lawsuit. (Compl. [Doc. 1.] at 1.) The complaint alleges five state-based causes of action. First, Aaronson claims that Vital Pharm violated Cal. Bus. & Prof. Code § 17200 by failing to make known the risks inherent in Redline and by deceptively promoting Redline as having approved and unique drug-qualities. (Id. at 13). Second, he alleges that Vital Pharm disseminated deceptive representations that wrongly promote Redline as a safe and healthy supplement in violation of Cal. Bus. & Prof. Code § 17500. (Id. at 15.) Third, Aaronson contends that Vital Pharm fraudulently concealed the dangers and risks associated with using Redline. (Id. at 16.) Fourth, Aaronson alleges that Vital Pharm breached the implied warranty of fitness by representing itself as reputable and its product as safe for enhancing energy and promoting weight loss. (Id. at 17-18.) Fifth, Aaronson alleges that Vital Pharm breached an express warranty by marketing its product as safe when in fact it is not, and failing to warn of the risks associated with its use. (Id. at 19.)

Vital Pharm now seeks to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(6) and 9(b). Additionally, Vital Pharm asserts that Aaronson's first two claims invade the FDA and FTC's primary jurisdiction, and asks the Court to exercise its discretion to dismiss the claims.

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¹ Aaronson's first complaint actually alleges seven causes of action, the last two of which were voluntarily withdrawn in his opposition brief. (*Pl. Opp.* [Doc. 7] at 15-16.)

II. <u>Discussion</u>.

A. <u>Dismissal Under the Primary Jurisdiction Doctrine.</u>

Vital Pharm argues that the first two causes of action should be dismissed or stayed under the primary jurisdiction doctrine. This doctrine "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires resolution of issues which, under a regulatory scheme, have been placed within special competence of an administrative body, in which case the judicial process is suspended pending referral of such issues to the administrative body for its views." United States v. Western Pac. R.R. Co., 352 U.S. 59, 64 (1956) (citing General American Tank Car Corp. v. El Dorado Terminal Co., 308 U.S. 422, 433 (1940)). The doctrine is applied at the court's discretion, and courts typically look to factors including whether adjudication of the issue requires the administrative body's expertise and whether there is a need for uniformity within the area of regulation. Syntek Semiconductor Co., Ltd. v. Microchip Technology, Inc., 307 F.3d 775, 781 (9th Cir. 2002) (citing United States v. General Dynamics Corp., 828 F.3d 1356, 1362 (9th Cir. 1987)).

Aaronson's first cause of action challenges Vital Pharm's "design, testing, manufacture, assembly, development, marketing, advertising and labeling" of Redline on the bases that the product has a "harmful impact upon members of the general public and the Class who purchased and used the Product for its intended and foreseeable purpose...." (Compl., at 13.) Aaronson's second cause of action alleges that Vital Pharm "disseminated, or caused to be disseminated, deceptive representations that promote the Product as a safe and healthy dietary supplement... but minimize, and fail to adequately warn the public of, the dangers and health risks associated with use of [Redline] or the proper dosage...." (Id. at 15.) As relief for these claims, Aaronson seeks an order enjoining the alleged wrongful practices. (Id. at 23.)

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Vital Pharm asserts that the FDA and FTC's special expertise are needed to adjudicate these claims, pointing out that the safety of dietary supplements is not regulated until after they enter the market. (MTD at 5-6.)² Vital Pharm further argues that the relief sought by Aaronson could lead to inconsistent product regulation, a result that primary jurisdiction seeks to avoid. (*Id.* at 6-7.) The Court will evaluate these arguments separately.

1. Redline's Safety

Cases raising issues of fact that do not fall within the traditional expertise of judges or cases requiring the expertise of administrative authority should be relinquished to the agency established by Congress to regulate the subject matter. Far East Conference v. United States, 342 U.S. 570, 574 (1952). The FDA, more than the average consumer, knows how to weigh conflicting studies and determine the most accurate and up-to-date information regarding product safety. Premo Pharm. Labs, Inc. v. United States, 629 F.2d 795, 803 (2nd Cir. 1980). Although courts can resolve whether a product has been approved as safe, the question of whether a product should be approved as safe requires the FDA's expertise. Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005).

Aaronson's first two claims are based on the contention that Redline is not safe. Aaronson supports this premise by attacking several of Redline's key ingredients (i.e., Yohimbine, Vinpocetine, Tyrosine, and 5-Hydroxtryptophan) (Compl. at 5-6), and by citing numerous studies that he claims discuss the dangers of these ingredients. (Id. at 4, n. 2-3; 5, n. 7-9.) These allegations make clear that in order to evaluate Aaronson's first two causes of action, the Court will likely need to evaluate conflicting studies and

² Although Vital Pharm seeks to dismiss the first two counts on grounds of primary jurisdiction. Agronson opposed the motion by primarily arguing that California law is not preempted by the FDA. (*Pl. Opp.* at 4-8.) Aaronson is correct that preemption does not apply; unfortunately, this is an issue of primary jurisdiction, not preemption.

determine whether Redline and/or it's ingredients should be approved as safe. Under the primary-jurisdiction doctrine, these issues are best suited for the FDA.

Additionally, the Dietary Supplement Health and Education Act of 1994 (DSHEA) provides that the supplement manufacturer is responsible for ensuring that a supplement is safe before it is marketed and the FDA is responsible for taking action against an unsafe supplement after it reaches the market. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.). Because Redline is already on the market, the DSHEA makes the FDA responsible for its regulation. Accordingly, the FDA has both the expertise and the authority to determine whether Redline is safe, and the Court believes the FDA is in the better position to make that determination.

2. <u>Uniform Regulation</u>

The primary jurisdiction doctrine is often invoked where a state-law decision could interfere with a federal regulatory scheme. See Brotherhood of R.R. Trainmen v. Jacksonville Terminal Co., 394 U.S. 369, 381-82 (1969); U.S. v. General Dynamics Corp., 828 F.2d 1356, 1362-63 (9th Cir. 1987) (discussing United States v. Western Pacific R.R., 352 U.S. 59, 65 (1956)).

Under the DSHEA's injunction provision, district courts are given jurisdiction to issue injunctions for violations of section 331, which prohibits the introduction into interstate commerce of a dietary supplement that is unsafe.³ 21 U.S.C.A. § 332(a) (West 2009). However, an action for an injunction under the DSHEA must be brought by the FDA, as there is no provision for private rights of action.

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³ Section 331(v) prohibits "The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b...." 21 U.S.C.A. § 331(v) (West 2009).

Aaronson seeks relief under California law, which if granted would enjoin the sales and labeling of Redline only in California. (*Compl.* at 22-23.) But until the FDA has had an opportunity to determine if Redline is safe, such an injunction would be premature and would interfere with the DSHEA's uniform scheme. In short, the FDA's unique ability to discern scientific data and ensure uniform regulation in the field of dietary supplements weigh in favor of dismissing Aaronson's first two claims on the grounds of the FDA's primary jurisdiction.

B. Motion to Dismiss under Rule 9(b).

Complaints alleging fraud must meet the pleading requirements of Federal Rule of Civil Procedure 9(b), which provides that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). A plaintiff must specifically identify the allegedly fraudulent statements or acts of fraud. Kaplan v. Rose, 49 F.3d 1363, 1370 (9th Cir. 1994). This requires the plaintiff to plead evidentiary facts including the dates, times, places and person associated with each misrepresentation or act of fraud. In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548-49 n.7 (9th Cir. 1994) (en banc) (superseded by statute on other grounds); Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993).

The particularity requirement serves four central purposes: it (1) "prevents the filing of a complaint as a pretext for the discovery of unknown wrongs," (2) "ensures that allegations of fraud are specific enough to give defendants notice of the particular misconduct ... so that they can defend against the charge and not just deny that they have done anything wrong," (3) "protects potential defendants – especially professionals whose reputations in their fields of expertise are most sensitive to slander – from the harm that comes from being charged with the commission of fraudulent acts," and (4) "prohibit[s] a plaintiff from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985) (internal citations omitted).

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Allegations of fraudulent concealment are subject to the Rule 9(b) requirement that the circumstances constituting fraud be pled with particularity. Rutledge v. Boston Woven Hose & Rubber Co., 576 F.2d 248, 250 (9th Cir. 1978) (finding that conclusory allegations of fraudulent concealment did not meet 9(b) requirements); Suckow Borax Mines Consol. v. Borax Consol., 185 F.2d 196, 209 (9th Cir. 1951) (holding that "bare allegations of fraudulent concealment" without supporting facts did not meet the requirement of 9(b)). Although conclusory allegations of fraudulent concealment will not survive under 9(b) standards, the Ninth Circuit has held that pleadings which provide the time, place and nature of the alleged fraudulent activities, such that the defendant can prepare an adequate answer, are sufficient. Bosse v. Crowell, Collier and MacMillan, 565 F.2d 602, 611 (9th Cir. 1977); Walling v. Beverly Enterprises, 476 F.2d 393, 397 (9th Cir. 1973).

Vital Pharm contends that Aaronson's fraudulent concealment claim fails to meet the particularity requirements of Rule 9(b). (MTD at 15-16.) Aaronson disagrees, arguing that by incorporating his factual allegations into each of his causes of action, he has given Vital Pharm sufficient notice of the claim. (*Pl. Opp.* at 14.)

While not a model of specificity, the complaint charges that Vital Pharm knew Redline had risks associated with its use, yet kept those risks hidden from Aaronson and other consumers. (*Compl.* at 16.) The risks are enumerated and specific statements made by Vital Pharm about Redline are set out in detail. (*Id.* at 4-9.) Accordingly, the Court finds that Aaronson has pled the claim with sufficient particularity.

C. <u>Motion to Dismiss under Rule 12(b)(6).</u>

The Court must dismiss a cause of action for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6) tests the complaint's sufficiency. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). Dismissal is proper only where the plaintiff's complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. Id.

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All material allegations in the complaint, "even if doubtful in fact," are assumed to be true. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555(2007). As the Supreme Court explained, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. (internal citations omitted). Instead, the allegations in the complaint "must be enough to raise a right to relief above the speculative level." Id.

Vital Pharm argues that Aaronson has failed to sufficiently state claims for either breach of implied or express warranty. It urges that the implied warranty claim must fail because Aaronson does not allege (1) reliance on the retail seller's statements, (2) notice, or (3) any cognizable damage. (MTD at 16.) Vital Pharm argues that the express warranty claim is insufficient for the same reasons, as well as its assertion that Aaronson did not allege facts sufficient to show that any description of Redline became a "basis of the bargain." (*Id.* at 18.)

1. <u>Breach of Implied Warranty.</u>

Reliance is an essential element to a claim for implied warranty of fitness for a particular purpose. The buyer must show that the party who breached the warranty knew or had reason to know that its statements were being relied upon, and also that he relied on those statements. <u>Keith v. Buchanan</u>, 220 Cal. Rptr. 392, 399 (Ct. App. 1985) (internal citations omitted).

California also has a general rule that actions for breach of implied warranty require privity of contract, and there is no privity between the original seller and a subsequent purchaser who was not a party to the original sale. See, Burr v. Sherwin Williams Co., 268 P.2d 1041, 1048 (Cal. 1954); Clemens v. Daimler Chrysler Corp., 534 F.3d 1017, 1023 (9th Cir. 2008). However, in transactions involving the sale of foods, drugs, and pesticides, there is a recognized exception which allows an implied warranty

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to run from the manufacturer to the ultimate consumer. Windham at Carmel Mtn. Ranch Assn. v. Superior Court, 135 Cal. Rptr. 2d 834, 839 (Ct. App. 2003); Burr, 268 P.2d at 1048, La Hue v. Coca-Cola Bottling, 314 P.2d 421, 422 (Cal. 1957) ("[A] manufacturer of food products or beverages, under modern conditions, impliedly warrants that his goods are wholesome and fit for human consumption, and such warranty is available to all who may suffer damage by reason of their use....")

Vital Pharm argues that Aaronson's implied warranty claim fails because Aaronson's complaint alleges that he relied on Vital Pharm's, and not the seller's, skill and judgment when selecting Redline. (MTD at 16.) Essentially, Vital Pharm's argument is that Aaronson lacks privity. Aaronson counters that Vital Pharm does sell Redline on its website, making it a seller as well as a manufacturer. (*Pl. Opp.* at 15-16.)

Although Aaronson does not go so far to allege that he relied on Vital Pharm's skill and judgment as a seller when selecting Redline, such reliance is unnecessary because Redline is a consumable product. Therefore Aaronson's implied warranty claim falls under the privity exception, allowing Aaronson to assert a claim against Vital Pharm notwithstanding the fact that Vital Pharm did not sell the product to him. Because Aaronson has pled the necessary reliance, he has met the minimum requirement for a breach of implied warranty for fitness claim.

Vital Pharm further attacks Aaronson's implied warranty claim by pointing out that Aaronson did not plead the statutorily required notice. (MTD at 16.)⁴ The California Uniform Commercial Code requires that a buyer claiming breach of implied warranty notify the seller of the breach within a reasonable time after discovery, or be barred from any remedy. Cal. U. Com. Code §2607 (3)(A) (West 2010).

In claims against a manufacturer of goods, however, California law does not require notice. See Greenman v. Yuba Power Products, Inc., 377 P.2d 897, 900 (Cal.

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⁴ Aaronson responds that he did notify Vital Pharm of its breach and seeks leave to amend his complaint to reflect this. (*Pl. Opp.* at 15.) As discussed below, this will not be necessary.

1963) (finding that the notice requirement is justified between parties to a sale in order to protect sellers from unduly delayed claims, but that there is no justification for imposing the requirement on claims against a manufacturer because "it will not occur to [a buyer] to give notice to one with whom he has had no dealings") (internal quotations and citation omitted); Crane v. Sears Roebuck & Co., 32 Cal. Rptr. 754, 757 (Ct. App. 1963) (finding no reason to require notice to the manufacture when not required by statute). Because Aaronson's claims are against Vital Pharm in its capacity as a manufacturer, not as a seller, notice is not required.

Finally, Vital Pharm urges that Aaronson's implied warranty claim should be dismissed for failure to allege damages. (MTD at 17.) In a successful breach of warranty claim, the victim of breach is entitled to damages based on "the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted, unless special circumstances show proximate damages of a different amount." Cal. U. Com. Code § 2714 (West 2010). A party seeking recovery for breach must first plead facts which support the basis for measuring damages, and then prove those damages at trial by any manner that is reasonable. Serian Brothers, Inc., v. Agri-Sun Nursery, 30 Cal. Rptr. 2d 382, 393-95 (Ct. App. 1994); Williams v. Lowenthal, 12 P.2d 75, 79 (Cal. 1932) (internal citations omitted).

Although Aaronson does not specify the amount of his damages, his damage claim is based on the difference in value between what he paid for Redline and its current value after learning of its alleged risks. He specifies that the actual amount of damages will be determined at trial. (*Pl. Opp.* at 18.) By incorporating the factual allegations to support these claims, Aaronson has sufficiently pled damages.

2. <u>Breach of Express Warranty</u>

Vital Pharm asserts that Aaronson's express warranty claim should fail for the same reasons as his implied warranty claim. For the reasons addressed above, the Court

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is not persuaded by Vital Pharm's arguments. Vital Pharm, however, also argues that the express warranty claim should be dismissed because Aaronson did not allege that he understood any promise made by the seller that became the "basis of the bargain." (MTD at 18.)

Statements made by a manufacturer through its advertising efforts can be construed as warranty statements. <u>Keith v. Buchanan</u>, 220 Cal. Rptr. 392, 396 (Ct. App. 1985). A buyer does not need to show that he relied on such statements to the extent that he would not have made the purchase without them, but only that they played a role in his purchasing decision. <u>Id.</u> at 397.

Vital Pharm argues that because Aaronson does not allege that he ever read any statement made by Vital Pharm, there is no way any of its statements could have become part of the "basis of the bargain." (MTD at 18.) Indeed, Aaronson does frame his express warranty claim "on information and [belief]... that [Vital Pharm] made different express warranties...." (Compl. at 19.) However, in paragraph 21 Aaronson alleges that "[Vital Pharm] presents itself as a reputable, reliable and safe manufacturer of dietary supplements, and [Aaronson] relied on this and other representations... in purchasing and using the product." (Id. at 9.) Although Aaronson's allegation should not serve as a model for drafting complaints, it does allow an inference to be drawn that Aaronson knew about Vital Pharm's safety claims when deciding to purchase and use Redline. Identification of the specific statements used by Aaronson in his purchasing decision are an appropriate avenue for discovery, but at this stage Aaronson has identified adequate facts to establish a warranty that was a "basis of the bargain." Accordingly Aaronson has sufficiently stated a breach of express warranty claim.

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IV. CONCLUSION AND ORDER

For the reasons stated above, the Court GRANTS WITHOUT PREJUDICE the 3 motion to dismiss the first two causes of action and DENIES the motion as to the 4 remaining causes of action.

IT IS SO ORDERED.

DATED: February 17, 2010

Hon. Thomas J. Whelan United States District Judge

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